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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

SALIX PHARMACEUTICALS, INC.,  
SALIX PHARMACEUTICALS, LTD.,  
ALFASIGMA S.P.A. AND BAUSCH  
HEALTH IRELAND LTD.

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS OF  
NEW YORK, LLC, AND AMNEAL  
EU, LIMITED

Case No.: 1:24-cv-04607-ESK-AMD  
Motion Date: January 6, 2025  
ORAL ARGUMENT REQUESTED  
FILED UNDER SEAL

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Defendants.

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**REPLY IN SUPPORT OF  
PLAINTIFFS' MOTION TO CONSOLIDATE**

## **I. INTRODUCTION**

Plaintiffs have moved to consolidate five cases pending before this Court. ECF Nos. 66, 66-1. Amneal does not oppose consolidation provided it “is not used to prejudicially delay the overall schedule or resolution of Amneal’s case beyond the schedule proposed by Amneal.” *See* Amneal’s Response to Plaintiffs’ Mot. to Consolidate (“Response”) at 1, ECF No. 73. As such, Amneal offers no basis for the Court to deny Plaintiffs’ motion.

Instead, Amneal confirms the five cases present common questions and consolidation would best serve judicial economy. The Court and the parties can manage case schedules appropriately to protect against any possibility of prejudice to Amneal or other defendants. As demonstrated below and in Plaintiffs’ motion to consolidate, this Court should consolidate the five cases under Federal Rule of Civil Procedure 42(a).<sup>1</sup>

## **II. CONSOLIDATION WOULD PROMOTE JUDICIAL ECONOMY**

Plaintiffs and Amneal agree this Court should weigh judicial economy against “the potential for new delays, expense, confusion, or prejudice” in deciding whether to consolidate these actions. Response at 5 (citing *Cima Labs, Inc. v Actavis*

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<sup>1</sup> Amneal asserts that Plaintiffs filed these actions “in bad faith” because “related patents have already been found invalid.” Response at 2-3. Plaintiffs strongly disagree. They rebutted this argument their Pre-Motion Letter On Partial Motion to Dismiss Counterclaims. ECF No. 48. Regardless, this argument is irrelevant to the pending motion to consolidate.

*Grp. HP*, No. 06-1970, 2007 WL 1672229, at \*6 (D.N.J. June 7, 2007) (additional citations omitted)).

Despite this agreement, Amneal erroneously suggests that *any* delay or prejudice to Amneal makes consolidation inappropriate. Not so. This Court should also weigh the substantial judicial economy benefits of consolidation with its ability to minimize any delay or prejudice through appropriate case management. *See Waste Distillation Tech., Inc. v. Pan Am. Res., Inc.*, 775 F. Supp. 759, 761 (D. Del. 1991) (granting consolidation after finding it would “save witness time and expense, avoid duplicitous filings, and eliminate the risk of inconsistent results between two proceedings”).

Amneal also incorrectly contends Plaintiffs “strategic[ally] flip-flop[ped]” regarding consolidation because Plaintiffs previously opposed consolidation when proposed by Amneal. Response at 1; ECF No. 39. Plaintiffs revised their position on consolidation because there are now *five* cases involving the same FDA-approved drug product, patents, and discovery issues. Additionally, the *Norwich* Action, No. 24-7140, was before Judge Kirsch when Plaintiffs previously opposed consolidation. The *Norwich* Action has since been reassigned to Judge Kiel and Magistrate Judge Donio. *Norwich* Action, No. 24-7140, ECF No. 30. In light of these developments, consolidation will significantly improve judicial economy. Indeed, Amneal previously extolled the benefits of consolidation, explaining “there are undisputed

common questions of fact, e.g. identical patents, identical prior art, identical witnesses, including inventors, identical invention development records, identical technology, etc., and common questions of law, e.g., claim construction, invalidity, secondary considerations, etc.” ECF No. 39 at 8. As Amneal correctly noted, “[t]he focus is not on what is different, but what is common” across the five cases. *Id.*<sup>2</sup>

**A. The Benefits of Judicial Economy Outweigh any Risk of Delay or Prejudice Cited by Amneal.**

Amneal does not dispute the five related cases raise substantial common questions. Amneal also does not dispute consolidation would best promote judicial economy. Like Amneal, the defendants in the *Zydus*, *Cipla*, and *Carnegie* Actions chose not to oppose consolidation.<sup>3</sup> Their silence confirms consolidation would best

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<sup>2</sup> Amneal also claims Plaintiffs did not meet and confer with defendants before filing their Motion to Consolidate. But there is no such requirement for a motion to consolidate. The Local Rules and this Court’s judicial preferences require meet and confers for discovery disputes, which this motion is not. See L. Civ. R. 37.1; Magistrate Judge Donio’s Judicial Preferences (citing L. Civ. R. 37.1). Further, Judge Kiel’s Rules and Procedures for “Motion Practice” do not apply to motions to consolidate. Regardless, Plaintiffs’ motion was not a surprise. Plaintiffs raised their intention to file a motion to consolidate on a status conference with the Court and Amneal previously proposed consolidation. Additionally, since the Motion was filed, lead counsel for Plaintiffs and Amneal have extensively discussed scheduling and the best approach for a consolidation protocol. See Exhibit A.

<sup>3</sup> *Salix Pharmaceuticals, Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 1:24-cv-09512-ESK-AMD ( “Zydus Action”); *Salix Pharmaceuticals, Inc. et al. v. Cipla USA et al.*, No. 1:24-cv-10213-ESK-AMD ( “Cipla Action”); and *Salix Pharmaceuticals, Inc. et al. v. Carnegie Pharmaceuticals LLC et al.*, No. 1:24-cv-10356-ESK-AMD ( “Carnegie Action”).

serve all parties. This concurrence makes sense, as the cases involve common plaintiffs, the same branded drug, overlapping patents, and substantially similar expert and fact discovery issues.

Any delay or prejudice resulting from consolidation would be minimal. Amneal makes much of an alleged prejudice if a revised schedule were to result in resolution of its case after the expiration of the 30-month statutory stay if FDA were to approve Amneal's ANDA product. Response at 1, 5-8. However, Amneal indisputably is *not* the first filer for generic rifaximin. As discussed in Plaintiffs' July 23 letter to the Court, ECF No. 48, Teva, not Amneal, was the first filer for generic rifaximin. And due to Teva's first-filer exclusivity under 21 U.S.C. §§ 355(j)(5)(B)(iv)(I), 355(j)(5)(D), Amneal cannot obtain FDA approval until *mid-2028*—long after the 30-month stay expires. ECF No. 48.<sup>4</sup> The possibility of this alleged prejudice to Amneal is therefore remote.

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<sup>4</sup> See also Bausch Health Cos. Inc.'s Form 10-K (Feb. 24, 2021), available at <https://ir.bauschhealth.com/~media/Files/V/Valeant-IR/reports-and-presentations/2021-bhc-annual-report.pdf> (last accessed Dec. 30, 2024) (Bausch's agreement with Actavis (now Teva) authorizes entry on January 1, 2028); *Norwich Pharms., Inc. v. Becerra*, 703 F. Supp. 3d 1, 13 n.3 (D.D.C. 2023) ("Teva's asserted right to a period of 180-days of generic exclusivity."); see also *Patent Certifications and Suitability Petitions*, U.S. FOOD & DRUG ADMINISTRATION (June 28 2024), available at <https://www.fda.gov/media/166048/download?attachment> (last accessed Dec. 30, 2024) (the first ANDA for rifaximin was submitted on December 18, 2015).

Amneal also misleadingly suggests “significant fact discovery has already occurred.” Response at 7. To the contrary, the parties have yet to depose a single witness, and only very limited initial fact discovery occurred. Amneal has provided no evidence that consolidation will significantly delay discovery. The efficiencies created across the five cases would substantially outweigh any minimal delay to accommodate the newer actions.

**B. The Court and Parties Can Manage the Case Schedules to Ensure Timely Resolution.**

Since Plaintiffs filed the Motion to Consolidate, counsel for Plaintiffs and Amneal have extensively discussed a proposed consolidated schedule that will allow resolution of the Amneal Action before the 30-month statutory stay expires. *See* Ex. A. Plaintiffs also have initiated discussions with counsel for the Zydus, Cipla, and Carnegie defendants about a schedule to accommodate all parties. *See* Exs. B-D. The most recent proposal between Plaintiffs and Amneal regarding an appropriate case schedule shows the progress of these discussions. Ex. E. While negotiations are ongoing, the parties are working in good faith to adopt an agreed consolidated schedule.

To ensure judicial efficiency, this Court should consolidate these actions for discovery. Plaintiffs have not proposed that the Court would proceed with a consolidated *trial* in these actions and believe it would be inappropriate at this time to set a trial date or schedule other pre-trial deadlines. Ex. E. Plaintiffs expect this

Court will, based on the progress of the cases, set trial dates according to its own procedures.

### **III. CONCLUSION**

For the foregoing reasons, this Court should grant the motion to consolidate.

Dated: December 30, 2024

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**CERTIFICATE OF SERVICE**

I certify that a copy of the foregoing has been served upon all counsel of record via the Court's ECF system on December 30, 2024.

*s/ Harvey Bartle IV*

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